

Attorney Docket No.: **KUZ0032US.NP**
Inventors: **Hashimoto et al.**
Serial No.: **10/584,739**
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REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11 have been amended. Support for these amendments is provided throughout the specification, for example at pages 8-13 as well as in the examples of patch preparations beginning at page 17. No new matter has been added. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Claim Objection

The Examiner has objected to claim 1 for use of the word "principal" instead of "principle". It is respectfully pointed out that the term "principal" in the specification and claims is used as an adjective to describe a main chain of a rubber-system macromolecule. The terms "main" and "principal", when used as adjectives, are synonyms. Accordingly, Applicants believe use of the word "principal" in the specification is correct. Reconsideration of this objection is therefore respectfully requested.

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II. Rejection of Claims 1-11 under 35 U.S.C. 112, second paragraph

Claims 1-11 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 1, the Examiner suggests that it is unclear whether the UVA or UVB blocker is in the adhesive base or merely present in the patch. Further, with respect to claim 10 which depends from claim 1, the Examiner suggests that there is no antecedent basis for tackifier. The Examiner also suggests that the recitation of 10 to 20 mass % in claim 10 is indefinite since it is unclear what this mass is relative to.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to clarify that the UVA or UVB block is in the adhesive base. Further Applicants have amended claim 10 to depend from claim 8 which provides antecedent basis for tackifier and to recite 10 to 20 mass % relative to total amount of adhesive base. Support for this amendment is provided in the specification at pages 13-14.

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Withdrawal of this rejection under 35 U.S.C. 112, second paragraph is respectfully requested.

III. Rejection of Claims 1-6, 8, 10 and 11 under 35 U.S.C 102(b) and claims 1-6 and 8-11 under 35 U.S.C. 103(a)

Claims 1-6, 8, 10 and 11 have been rejected under 35 U.S.C. 102(b) as being anticipated by Tsuruda et al. (WO 01/68061 and U.S. Patent 6,924,410).

Claims 1-6 and 8-11 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda et al.

Applicants respectfully traverse these rejections.

Tsuruda et al. discloses a patch containing UV blocker in the backing layer.

Claims of the instant application have been amended to recite the adhesive base further containing 0.5 to 20 mass % relative to entire amount of the preparation of a UVA blocker and/or a UVB blocker as a stabilizer for the rubber-system macromolecule.

Since Tsuruda et al. does not teach or suggest addition of a UVA/UVB blocker to the adhesive base, this reference cannot anticipate nor render obvious the instant claimed invention.

Withdrawal of these rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) is respectfully requested.

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**IV. Rejection of Claims 1-6, 8, 10 and 11 under 35 U.S.C.
103(a)**

Claims 1-6, 8, 10 and 11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda et al. in view of Honda (U.S. Patent 5,637,293).

Applicants respectfully traverse this rejection.

As discussed in paragraph III, *supra*, claims of the instant application have been amended to recite the adhesive base further containing 0.5 to 20 mass % relative to entire amount of the preparation of a UVA blocker and/or a UVB blocker as a stabilizer for the rubber-system macromolecule.

Tsuruda et al. does not teach addition of a UVA/UVB blocker to an adhesive base.

Honda et al. also does not teach addition of a UVA/UVB blocker to an adhesive base.

Accordingly, these references do not teach or suggest all limitations of the claims and therefore cannot render obvious the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. 103(a) is respectfully requested.

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**V. Rejection of Claims 1-8, 10 and 11 under 35 U.S.C.
103(a)**

Claims 1-8, 10 and 11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda et al. in view of Yasukochi et al. (U.S. Patent Application Publication No. 2005/0053646). The Examiner has acknowledged that Tsuruda et al. do not teach use of UV blocking agents in the adhesive base. However, the Examiner suggests that Yasukochi et al. teach that the adhesives of these patches may contain a variety of additives including UV-absorbing agents. The Examiner suggests that Yasukochi et al. teach that these UV-absorbing agents are preferably used in an amount of 10% or less related to the total weight of the adhesive composition.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully point out that the claims have been amended to be drawn to a patch preparation comprising a support and an adhesive base, the adhesive base containing 8 to 50 mass % relative to total amount of the adhesive base of a rubber-system macromolecule having a double bond at least in a principal chain thereof and 0.1 to 10 mass % relative to entire amount of the preparation of a nonsteroidal anti-inflammatory analgesic drug, and the

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adhesive base further containing 0.5 to 20 mass % relative to entire amount of the preparation of a UVA blocker and/or a UVB blocker as a stabilizer for the rubber-system macromolecule. As taught in the specification, for example at page 8, page 10 and page 11, a patch preparation with the claimed respective amounts of components retains functional stability.

Applicants respectfully disagree with the Examiner that the skilled artisan would combine the cited teachings of Tsuruda et al. and Yasukochi et al. to arrive at the instant claimed invention with predictable results.

As acknowledged by the Examiner, Tsuruda et al. does not teach or suggest use of UV blocking agents in the adhesive base. In fact, Tsuruda et al. teaches that incorporating an ultraviolet absorbent in the base creates a safety problem due to the absorbent's direct contact with or absorption into the skin. See col. 1, lines 40-45 of Tsuruda et al.

Further, while Yasukochi et al. included a UV absorbent in the adhesive base, the adhesive base did not further contain 8 to 50 mass % relative to total amount of the adhesive base of a rubber-system macromolecule having a double bond at least in a principal chain thereof. Instead,

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the adhesive of Yasukochi et al. contains one or more kinds of acrylic or methacrylic monomer units.

Thus, the cited combination of references provides no reasonable expectation of success that the instant claimed patch with the specified respective amounts of each component would retain functional stability.

The development of functionally stable, safe patch preparations with acceptable adhesive properties is unpredictable. This is made quite in the art cited by the Examiner as well as the instant application.

For example, Honda teaches that addition of a fatty acid ester or a fatty acid glyceride was required to prevent separation of an ultraviolet absorber from a conventional kojic acid containing preparation. Yasukochi et al. teaches that a boron-containing compound as a crosslinking agent and a polymer with a hydroxy group are required to produce an adhesive having sufficient tackiness and cohesiveness. Other crosslinking agents caused decomposition, denaturing of drug and skin irritation, while use of inorganic compounds caused problems with solubility.

Also see the instant specification at, for example, page 9, wherein it is taught that 0.5 to 20 mass % relative to entire amount of the preparation of a UVA blocker and/or a

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UVB blocker was selected to prevent inhibition of skin penetrability of the NSAID, page 10 wherein it is taught that 0.1 to 10 mass % relative to entire amount of the preparation of a nonsteroidal anti-inflammatory analgesic drug was selected to enable and anti-inflammatory analgesic effect to be fully exhibited while achieving preparation stability; and page 11 wherein it is taught that 8 to 50 mass % relative to total amount of the adhesive base of a rubber-system macromolecule having a double bond at least in a principal chain thereof provides for cohesive strength and ease of handling.

The cited combination of references is in no way predictive of the claimed combination of components in the specified ranges providing a useful patch with these properties.

Withdrawal of this rejection is therefore respectfully requested.

VI. Provisional Obviousness-type Double Patenting Rejection

Claims 1-4 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5 and 6 of copending Application No. 10/552,173.

Applicants respectfully traverse this rejection.

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Claims of the instant application have been amended to recite the adhesive base further containing 0.5 to 20 mass % relative to entire amount of the preparation of a UVA blocker and/or a UVB blocker as a stabilizer for the rubber-system macromolecule.

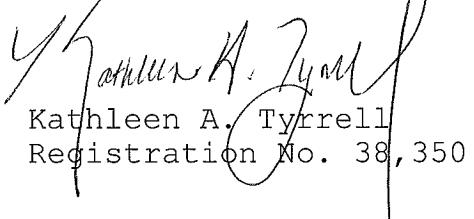
In contrast, in claims 1, 5 and 6 of copending Application No. 10/552,173, ultraviolet transmittance is limited by the backing layer.

Withdrawal of this rejection is respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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